K070732

Summary of Safety and Effectiveness

JUL - 9 2007

Manufacturer:	Smiths Medical PM, Inc.
Address:	N7 W22025 Johnson Drive Waukesha, WI 53186
Telephone:	(262) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	February 28, 2007
Proprietary Name:	BCI® Autocorr™ 3304 Digital Pulse Oximeter
Common/Classification Name:	Pulse Oximeter
Predicate Devices:	BCI® Autocorr™ 3304 Digital Pulse Oximeter (K962156)

Device Description:

The subject device is the same as the legally marketed predicate device BCI® 3304 Autocorr™ Digital Pulse Oximeter (K962156) with one minor change to the labeling that does not raise new questions of safety and efficacy. This pulse oximeter was originally cleared with the current algorithms. However, it was not clinically validated under motion conditions and no motion claims were made. The aim of this premarket submission is to obtain clearance for an additional motion claim.

The 3304 Autocorr™ pulse oximeter is designed to provide full featured monitoring capabilities in a light weight, transportable design. The system consists of a small table top oximeter with a wall mount charger. The system features an SpO_2 probe interface, display of patient data via an LED display (SpO_2, Pulse Rate, Pulse Strength), system status LEDs (Probe, Lo Batt, Silence, Alarm, Artifiact, Search), and the function keypad area consisting of eight keys (O/I, ID/Clear, Up and Down Arrows, Alarm Select, Alarm Silence, Alarm Volume, Pulse Volume). The oximeter has a printer/pc port that is used for data communication, an optional analog output and an optional digital alarm adapter for a remote location.

This Special 510(k) covers the labeling modification of BCI® Autocorr™ 3304 Digital Pulse Oximeter that was cleared under 510(k) K962156. The modification involves revising the 3304 labeling to add pulse oximetry performance specifications with motion. Results from clinical evaluation are provided to support the labeling change. No significant device modifications have been made to the 3304. The labeling change does not affect the intended use or alter the fundamental scientific technology of the device.

Intended Use:

The intended use is identical to that originally submitted for BCI® Autocorr™ 3304 pulse oximeter. As stated per K962156, the intended use is as follows:

The 3304 provides fast, reliable SpO_2, pulse rate and pulse strength measurements. It may be used in the hospital or clinical environment, during emergency air or land transport and in the home. The oximeter will operate accurately over an ambient temperature range of 32 to 104°F (0 to 40°C). The oximeter works with all BCI oximetry probes providing SpO_2 and pulse rate on all patients from neonate to adult. The oximeter permits continuous patient monitoring with adjustable alarm limits as well as visible and audible alarm signals.

Summary of Technological Characteristics of the Device Compared to the Legally Marketed Predicate Device:

No significant design modifications have been made to the BCI® Autocorr™ 3304 Pulse Oximeter.

No significant changes have been made to the software or hardware of the 3304 pulse oximeter.

Performance Testing:

Previous performance testing including EMC, electrical, mechanical durability, clinical desaturation studies, safety (operator and patient), and temperature/humidity was submitted in K962156. Additional clinical testing, submitted in Section 7 of this submission, was performed to support the labeling change.

Additional Clinical Testing:

The intent of the clinical investigation was to determine the oxygen saturation accuracy specifications for the model 3304 during controlled motion. Ten paid, adult, volunteer subjects participated in this trial. They varied in age from 21 to 36 years. There were three Black or African American and seven White subjects enrolled. They were three females and seven males. Nine subjects described themselves ethnically as non-Hispanic or non-Latino and one subject described himself as Hispanic or Latino.

This study was a descriptive, cross-sectional investigation of healthy, human subjects comparing Model 3304 pulse oximeter determined oxygen saturation (SpO_2) values during motion (test condition) to CO-oximeter determined functional oxygen saturation (SaO_2) values (reference condition). Additional Model 3304 pulse oximeters which were not subjected to motion were used as a control and to determine stable plateaus in the oxygen saturation readings. The study was conducted at oxygen concentrations that targeted an even distribution over the SaO_2 range of 70 to 100%-SaO_2. The motion protocol used in this study consisted of tapping and rubbing motions of randomly varied frequency and amplitude. The maximum frequency was 300 cycles/minute (5 Hz). The maximum height was generally approximately 2.5 cm. The data were electronically gathered by the Smiths Medical PM, Inc. proprietary CRAWDADS program and

analyzed by the CRAWDADS_EXCEL template. Manual recording of the data was also made.

Acceptance Criteria: The acceptance pass criteria for this study was less than 3%-SpO_2.

Results:

	Motion Desaturation Trial Motion Condition (%SpO_2)	Performance Specification (%SpO_2)
A_{RMS}	2.95	3.00
Standard Deviation	2.84	-
Average Difference	-0.82	-

The Smiths Medical PM, Inc. Model 3304 Pulse Oximeter operated within the pass criterion of less than 3%-SpO_2 evenly distributed over the range 70 to 100%-SaO_2 during motion of controlled amplitude and frequency. There were no adverse events or adverse device effects in this study.

The table below compares the summarized results for the SMPM 3304 Pulse Oximeter in the control condition (non-motion) of this study to the results in the original SMPM 3304 Pulse Oximeter desaturation trial performed for accuracy testing on 7-8 May 1996.

	Motion Desaturation Trial Control Condition (non-motion) (%-SpO_2)	Accuracy Desaturation Trial Original (non-motion) (%-SpO_2)
Average Difference	0.05	0.83
Standard Deviation	1.69	1.70
A_{RMS}	1.69	1.89[1]

These results show that the 3304 pulse oximeter in the control condition (non-motion) in this trial performed with an accuracy comparable to the 3304 pulse oximeter in the original desaturation trial performed for accuracy testing on 7-8 May 2006. In both cases, the sensors were not in motion during the study.

Summary of Labeling Change:

The labeling modification consists of detailing SpO_2 accuracy specifications within the device specifications according to motion and no motion conditions. Please note that the accuracy of SpO_2 measurements detected by the 3304 pulse oximeter has not changed. The labeling modification is detailed as follows:

[1]This value is an estimate of the A_{RMS} using the formula $A_{RMS}\ (est.) = \sqrt{(Average\ \ Difference^2 + Std\ Dev^2)}$.

SpO_2 Accuracy: Motion: 70-100% ± 3%
50-69% not defined

No Motion:	70-100% ± 2% 50-69% ± 3% <50% not defined	(identical to original K962156)

These motion accuracy specifications are applicable with the following sensors: 1300 (adult), 1301 (pediatric), 1302 (neonate), 1303 (infant) disposable sensors. This labeling modification, along with a list of applicable sensors, will be made to the device specifications located in the functional specifications, operational manual and draft promotional literature.

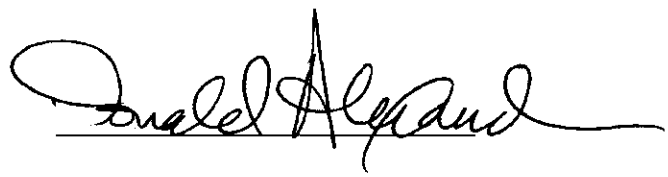
Conclusion:

The results of the clinical test support the labeling change and do not raise new questions of safety or effectiveness when compared to the legally marketed predicate device.

Supporting information per this premarket submission confirms that the BCI® Autocorr™ 3304 Digital Pulse Oximeter is substantially equivalent to its predicate (K962156).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,



Donald Alexander
VP Regulatory Affairs
Smiths Medical PM, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2007

Mr. Donald Alexander
Vice President Regulatory Affairs
Smith Medial PM, Incorporated
N7 W22025 Johnson Drive
Waukesha, Wisconsin 53186-1856

Re: K070732
Trade/Device Name: BCI® Autocorr™ 3304 Digital Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 20, 2007
Received: June 22, 2007

Dear Mr. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

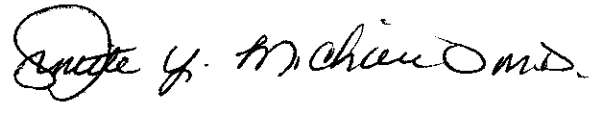
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: BCI® Autocorr™ 3304 Digital Pulse Oximeter

Indications for Use:

The 3304 provides fast, reliable SpO2, pulse rate and pulse strength measurements. It may be used in the hospital or clinical environment, during emergency air or land transport and in the home. The oximeter will operate accurately over an ambient temperature range of 32 to 104°F (0 to 40°C). The oximeter works with all BCI oximetry probes providing SpO_2 and pulse rate on all patients from neonate to adult. The oximeter permits patient monitoring with adjustable alarms limits as well as visible and audible alarm signals.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070732